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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,587	11/28/2000	Jean Francois Bloch	746220.0003 (58763.000003)	6164

21967 7590 07/01/2003

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EXAMINER

SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
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1636

16

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/722,587**

Applicant(s)  
**Bloch et al.**

Examiner  
**William Sandals**

Art Unit  
**1636**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 2, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above, claim(s) 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4-28 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Dec 21, 2001 is/are ☒ accepted or ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: ☐ approved ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 16
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-28, drawn to an in-vitro method for determining the activity of a substance, classified in class 436, subclass 86.
  - II. Claim 29, drawn to a process for development of new functional tests, classified in class 436, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I and II are unrelated because Group I is drawn to a method of determining the activity in vitro of a substance using a functional test. Group II is drawn to development of new functional tests. The development of new functional tests is not required for the method of Group I, and determining the activity of a substance is a limitation which is not required for the method of Group II. Therefore the method of Group I is biologically, physically, biochemically and patentably distinct from the method of Group II.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with David Mulligan, Esq. on May 20, 2003 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-28. Affirmation of this election must be made by applicant in replying to this Office action. Claim 29 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Priority***

6. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

7. The Declaration filed May 14, 2001 indicates that the claim of priority to international application PCT/FR99/03062 is made under 35 USC 119. The Utility Patent Application Transmittal filed November 28, 2000 indicates that the instant application is filed as a

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continuation of international application PCT/FR99/03062. It is assumed that the Utility Patent Application Transmittal filed November 28, 2000 is correct, that the instant application is filed as a continuation. Therefore, to correct the error in the Declaration, a new Declaration is required indicating the proper claim to priority under 35 USC 120.

8. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 153(b) as *follows*:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

#### ***Drawings***

9. The drawings as submitted on December 21, 2001, have been approved by the draftsman.

#### ***Specification***

10. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

#### ***Claim Objections***

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11. Claims 4-28 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must not depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4-28 have not been further treated on the merits.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fritsch et al. Fritsch et al. teach at the materials and methods section and at Figure 4, an *in vitro* method of testing a substance for activity on a protein. The test is done in the presence and absence of the substance. The test is done in the presence and absence of the protein. The protein is produced by *in vitro* transcription of a DNA encoding an estrogen receptor to produce an RNA and the *in vitro* translation of the RNA into protein. The DNA encoding an estrogen receptor has been inserted into an expression vector which contains a promoter. The RNA is translated into a protein *in vitro*. The RNA therefore, contains a ribosome binding site. The translated protein is allowed to bind to an estrogen receptor-binding DNA to assay the protein for its ability to bind to the estrogen receptor DNA binding site.

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14. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,360,714 (Seeger).

Seeger teaches at the Description of the Figures, at column 4, and at Examples 1-4, the *in vitro* transcription of a viral DNA to produce an RNA and the *in vitro* translation of the RNA into protein (DNA polymerase). The protein (DNA polymerase) is assayed in the presence and in the absence of its substrate DNA to test for activity. The test is also conducted in the presence and absence of the protein (DNA polymerase) (see figure 2A, lanes 3 and 4). The viral DNA is contained in a vector with a promoter. The RNA is translated into a protein *in vitro*, and therefore, contains a ribosome binding site.

15. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,767,233 (Zhang et al.).

Zhang et al. teach at example 5 the *in vitro* transcription of a viral DNA to produce an RNA then translation of the RNA to produce a protein (protease). The protein (protease) is then assayed in the presence and in the absence of a substrate for enzymatic activity. The assay is performed in the presence and in the absence of the protein. The viral DNA is contained in a plasmid which contains a promoter. The RNA is translated into a protein *in vitro*, and therefore, contains a ribosome binding site.

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***Conclusion***

16. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.

Examiner

June 26, 2003

  
JAMES KETTER  
PRIMARY EXAMINER